**Research Proposal**

**For**

**Doctoral (PhD) Degree in Faculty of Medicine and subject in Radiology**

**On the title**

# Comparative Evaluation of Masseter Muscle stiffness by Muscle hardness meter and Ultrasound elastography in patients with Temporomandibular disorders -A case control study

***Submitted to***

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**(Batch: 2020-21)**

**SUMANDEEP VIDYAPEETH DEEMED TO BE UNIVERSITY**

## Checklist for Ph.D. Research Proposal Submission

| Content | Yes/No/NA |
|---|---|
| 1. Covering letter of submission Signed by Investigators and forwarded by HOD/ Off. Incharge | Yes |
| 2. Title or cover page | Yes |
| 3. Introduction | Yes |
| 4. Aim and Objectives | Yes |
| 5. Review of literature | Yes |
| 6. Materials and methods | Yes |
| a. Study design | Yes |
| i. Place of study | Yes |
| ii. Source of data | Yes |
| iii. Related Approvals | Yes |
| iv. Sample Description | Yes |
| v. Time Scale of Study | Yes |
| vi. Selection Criteria | Yes |
| 1. Inclusion Criteria | Yes |
| 2. Exclusion Criteria | Yes |
| b. Material / Equipment for the study | Yes |
| c. Methodology | Yes |
| d. Informed consent form (ICF) for participants in research programmes involving studies on human beings. (In Gujarati and English) | Yes |
| e. Participant information sheet. (In Gujarati and English) | Yes |
| 7. Statistical method | Yes |
| 8. Ethical issues | Yes |
| 9. Feasibility issues | Yes |
| 10. Likely outcome/ benefits of study | Yes |
| 11. Conflict of interest | Yes |
| 12. Sponsors for the study, if any | Yes |
| 13. Source of fund, if any | Yes |
| 14. Expenditure Statement | Yes |
| 15. References (superscript and Vancouver style) | Yes |
| 16. Signature of Principal Investigator& Co-Investigators/PG Guide | Yes |

Research Scholar Research Supervisor Co-Supervisor

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## Introduction

The masseter muscle is a part of the stomatognathic system and aids in the physiological function of mastication, which is the first step in proper digestion. Impaired bite force and occlusal morphology, speech difficulties, and acute or persistent discomfort are among symptoms of masseter muscle pathologies.[1]

Temporomandibular disorders (TMDs) are a group of musculoskeletal disorders that affect the stomatognathic system. [2]TMDs is an umbrella term that embraces chronic pain conditions and dysfunction in the orofacial region affecting the masticatory muscles, the temporomandibular joints and their associated structures. [3]TMD is frequently linked to pain that originates in the muscles. The masticatory muscle examination is very valuable for diagnosing and monitoring muscle-related temporomandibular disorders and are commonly referred as Myofascial pain.[4]

Myofascial pain alone represents 45.3% of TMD diagnoses and is defined as a regional muscle pain associated with tenderness on palpation and referred pain.[5] Patients with Myofascial pain often complain about pain in the masseter muscle, as well as its hypertrophy, which clinically manifests with increased stiffness and tension.[6] Clinically, the muscle pain is linked to myofascial trigger points .These are hypersensitive points located in a taut band of a skeletal muscle, which can cause specific local or referred pain on stimulation and follows a reproducible pattern.[7] In patients with myofascial pain, specific biochemical pathways may be responsible for the increased stiffness and tenderness of affected muscles. Increased exposure to emotional stress in patients with Myofascial pain contributes to increased muscle tension manifesting as muscle stiffness and tenderness[8].

Biomechanical evaluation of affected muscles is important in basic and clinical research, including neuromuscular diseases, muscle injuries and sports training. When muscle fibres are damaged, muscles show shortening and hardening. Exercise of muscles induces fluid accumulation and an increase in the intramuscular pressure, and, consequently, changes muscle stiffness and thickness. For these reasons, the stiffness of skeletal muscles is widely used as an index in the fields of orthopaedics and sports medicine. Similarly, the stiffness of the masticatory muscles can aid in the diagnosis and treatment of Myofascial pain in patients with temporomandibular disorders.[9]

Several methods of assessing muscle stiffness have been developed. However, none of them have been introduced into routine clinical practice. My tonometry has been found to be reliable for measuring muscle stiffness in both larger muscles and smaller muscles, but it is not

commonly used for the assessment of dysarthria and TMD.[10] Electromyographic evaluation was also reported to be useful in monitoring the treatment of TMD.[11] Additionally, a portable muscle stiffness meter has been used in clinical research,[12] and strain wave elastography can be seen to be a very promising method. Muscle hardness meters have recently been developed.

Using this meter, we can make various studies of muscle conditions and the meter can provide us with a new physiologic parameter, Ashina et al showed a positive correlation between muscle hardness and tenderness in patients with chronic tensiontype headaches. However, very studies have been made regarding muscle hardness in patients with masticatory myofascial pain. Elastography has been validated in studies using phantoms of known stiffness and has also been compared to other methods like MRI.[13] Results of studies on other organs example trapezius show that agreement between radiologists is statistically significant.[11]However, despite promising results obtained in studies on healthy volunteers this method still needs to be tested on patients with increased muscle tonus (e.g. suffering from TMDs) and those undergoing interventions aimed at reducing muscle stiffness.[9]

Traditionally, the stiffness of tissues has been used as a marker of disease, through palpation. This concept has been extended within the field of ultrasound, with maps of tissue stiffness generated alongside anatomical images. Ultrasound is an essential modality within medical imaging, predominantly for assessing soft tissues. Recently, the additional tool of ultrasound elastography has become commercially available for further assessment of tissues, in addition to the standard B-mode and Doppler imaging. The elastic properties of tissues are different from the acoustic impedance used to create B mode imaging and the flow properties used within Doppler imaging, hence elastography provides a different form of tissue assessment and possibly showing pathology before it can be detected on B mode imaging. This may be of particular use in the musculoskeletal system where there is a wide spectrum of tissue specialisation. Elastography assesses the strain (stiffness) of these tissues in response to stress, through a variety of different methods.[14]

The term elastography was described by Ophir *et al*[15] as a method of portraying the strain properties of biological tissue. In strain, or compression elastography, a force (*i.e.*, stress) is applied from the transducer by repetitive manual pressure and the displacement (strain) is calculated from the return velocities of the tissues with respect to time. Measuring the displacement (strain) of the tissues secondary to an applied force (stress) gives a qualitative map of the elastic modulus distribution, termed an elastogram. This elastogram is colour-coded and often super-imposed on a grey-scale B mode image for anatomical localisation. True

quantitative measures cannot be taken from this elastogram, as the applied force is unknown. A semi-quantitative evaluation, however, can be determined from the ratio of the displacement of the tissue of interest and an adjacent structure, such as subcutaneous fat. This is measured in terms of Muscle elasticity index.[16,17]

## Need / Rationale of research work

The Temporomandibular disorders are prevalent in among 60% to 70% of the normal population and only around 15% exhibit the TMD symptoms.[2] Myofascial pain, one of the most common findings in TMD, is diagnosed on the basis of the presence of pain and tenderness by palpation. Myofascial pain is often associated with regional pain in tender areas, known as trigger points, which are expressed in taut bands of skeletal muscle and tendon. Clinically, the masticatory muscle associated with myofascial pain is hard and stiff on palpation.

Myofascial pain is a common condition, but the underlying mechanisms are still not fully understood. The pain associated with the TMDs causes masticatory dysfunction, affects activities of daily life and, in particular, leads to psychological problems. Clinicians highlight the role of addressing increased stiffness and tonus of the masseter muscle as part of the conservative treatment of TMD. Efforts to prevent or ameliorate TMD may therefore improve patient quality of life.[4]

The diagnosis depends on a subjective assessment by patients and clinicians; therefore, it is difficult to assess the disease objectively. However, this is a subjective finding by practised clinicians well-experienced in palpation. A clear objective assessment of masticatory muscle stiffness in patients with myofascial pain has yet to be made. Therefore, it is necessary to establish an effective method to objectively evaluate the severity of masticatory muscle stiffness and the effect of treatment on myofascial pain.

Various tools have been used to assess the stiffness in myofascial pain like Myotonometry, muscle hardness meter but its use in TMDs is limited. Although alterations in masseter muscles have been evaluated by EMG, this method has limitations, as the electrical signal is easily affected by the experimental environment.[10,11]

Ultrasonography (US) may be an alternative which can noninvasively depict the morphology and thickness of the masseter and other muscles situated superficial to the bone structures in the head and neck region. Elastography is a novel diagnostic tool and helps in evaluating the muscle stiffness both qualitatively in the form of an elastogram and quantitatively in terms of

muscle elasticity index. Elastographic studies performed in other organs like thyroid, trapezius and fibromyalgia have proven to be statistically significant.[16,17]

There are very few studies using strain wave elastography in the literature in patients with myofascial pain to assess the stiffness of the masseter muscles. The studies performed previously were conducted on small sample sizes and the results cannot be generalised to the entire population.

USG Elastography is a cost- effective diagnostic tool and has an added advantage of using non-ionising radiation. It's a real time imaging modality and the results are available rapidly in a short period of time. According to a systematic review by Olchowy et al[18], USG Elastography is a promising tool for the assessment of the masseter muscle stiffness, but the evidence is insufficient. Studies on larger groups are needed to determine the accuracy of elastography to characterize masticatory muscle disorders.

In the present study, the masseter muscle stiffness will be assessed by muscle hardness meter and strain wave elastography. The Masseter muscle elasticity index will be assessed in patients with Temporomandibular disorders and normal healthy adult volunteers. The results obtained will form a database for patients to compare the normal and altered values in patients with Myofascial pain. This way strain wave elastography can be used as a diagnostic tool to assess the masseter muscle stiffness. This can help in deciding the effective treatment plan for the patients with Myofascial pain thereby reducing the pain intensity and improving their quality of life.

**Null Hypothesis:**

There is no variation in the muscle stiffness assessed by elastography and muscle hardness meter in patients with temporomandibular disorders (myofascial pain) and healthy patients.

## Literature Review

**Ariji Y *et al., (2004)***[19] conducted a study to examine ultrasonographic appearances in female patients with temporomandibular disorder (TMD) associated with myofascial pain in comparison with healthy volunteers. The thickness of the masseter muscle in 25 female patients with TMD was measured at rest and at maximum contraction using ultrasonography. The visibility and width of the internal echogenic bands of the masseter muscle were also assessed and the muscle appearance was classified as 1 of 3 types: type I, characterized by the clear visibility of the fine bands; type II, thickening and weakened echo-intensity of the bands; type III, disappearance or reduction in number of the bands. There were significant differences in the thickness at rest and the increase ratio by contraction between the patient and control groups. The distribution of muscle types showed a significant difference between the 2 groups. The ultrasonographic features of the masseter muscle in TMD patients with myofascial pain were clarified and they might be related to muscle edema.

**Ariji Y *et al., (2013)***[20] investigated the relationship between the masseter muscle elasticity index (MEI) ratio obtained by sonographic elastography and the hardness measured by a hardness meter in healthy volunteers, and to clarify the characteristics of the masseter muscle hardness in temporomandibular disorder (TMD) patients with myofascial pain. Sonographic elastography images were obtained using a LOGIQ E9 (GE Healthcare), and the MEI ratios were calculated using Elasto Q software. The relationship between the MEI ratio and the masseter muscle hardness measured using a hardness meter was examined in 35 healthy volunteers. The MEI ratio in 8 TMD patients with myofascial pain was compared with that of the healthy volunteers. The MEI ratio was significantly correlated with the masseter muscle hardness. There was a significant difference between the MEI ratios of the symptomatic and asymptomatic sides in the TMD patients with myofascial pain. The MEI ratio of the symptomatic side in the TMD patients was larger than that on the right side of the healthy volunteers. The authors concluded that Sonographic elastography can be used to express the muscle hardness. It can be selected as a modality for showing the features of muscles with pain.

**Ariji Y *et al., (2013)***[21] investigated the intramuscular changes on sonographic elastography (SE) after low-level static contraction of the masseter muscle, to clarify the relationship with the total hardness and edematous change. Ten healthy volunteers performed sustained bilateral biting at 20% of maximal voluntary contraction for 10 min. The SE and magnetic resonance (MR) scans of the masseter muscles were performed before, immediately after, and 10 min after exercise. The masseter muscle elasticity index (MEI) ratio, muscle thickness, and intramuscular soft and hard areas distribution were evaluated on SE images. The signal to noise ratio (SNR), indicating the water content, was measured on MR images. The soft area ratio showed significant correlations with the water content expressed as SNR. The hard area ratio showed significant correlations with the total muscle hardness expressed as the MEI ratio. The authors concluded that Intramuscular soft and hard areas could be used both clinically and experimentally,

**Nakayama M et al., (2015)**[22] verified the use of a single coupling agent as a reference to obtain the elasticity index (EI) ratios and to investigate the EI ratios of the masseter muscles of healthy volunteers. Muscle phantoms with known elasticity (20, 40 and 60 kPa in the Young's modulus) were examined by strain-type sonoelastography using a coupling agent as the reference. Eight examiners tested soft (with 7 kPa) and hard (with 40 kpa) reference coupling agents separately. The correlation coefficients were determined between the EI ratio and Young's modulus of muscle phantoms. The interclass correlation coefficients were calculated for inter- and intraexaminer agreement. Strong correlations were found between the EI ratios and Young's modulus for both soft and hard references. The variations of the EI ratios were larger with soft coupling agents than those with hard coupling agents, and they increased in phantoms with 60 kPa elasticity. There were no differences in the EI ratios of the masseter muscle at rest between males and females or between the right and left sides. The ratio increased during clenching. The authors concluded that the hard reference coupling agent was suitable for obtaining EI ratio of the masseter muscle. No differences were found in the EI ratios of the masseter muscle either between sexes or between the right and left sides at rest, and the ratios increased with the widening of their variations during clenching.

## Aim and Objective

### Aim

To evaluate and compare the stiffness of masseter muscles by Muscle hardness meter and Ultrasound elastography in patients with Temporomandibular disorders and adult healthy volunteers

### Objectives

1. To evaluate the stiffness of masseter muscles by Muscle hardness meter
2. To evaluate the stiffness of masseter muscles through strain wave elastography by assessing Masseter muscle elasticity index in patients with Temporomandibular disorders
3. To evaluate the stiffness of masseter muscles through strain wave elastography by assessing Masseter muscle elasticity index in adult healthy volunteers
4. To compare the stiffness of masseter muscles through strain wave elastography by Masseter muscle elasticity index in patients with Temporomandibular disorders and adult healthy volunteers
5. To assess the intensity of masseter muscle pain by Visual analogue scale
6. To assess the correlation of stiffness of masseter muscles by Muscle hardness meter and Ultrasound elastography
7. To assess the correlation of pain intensity of masseter muscle and muscle stiffness of masseter muscle in patients with Temporomandibular disorders
8. To assess the thickness of Masseter muscle and corelate with the Masseter muscle elasticity index in cases and controls

## Materials and Proposed Methodology

I.**STUDY DESIGN:** Case control Study

i. **Place of study:** The study will be conducted at:

The Present study will be conducted in the Dept. of Oral Medicine and Radiology (OMR), K M Shah Dental College and Hospital and in the Department of Radiology, SBKS MI & RC and Dhiraj Hospital, Piparia, Vadodara, India.

**ii. Source of Data:**

- Department of Oral Medicine & Radiology, KMSDCH, Sumandeep Vidyapeeth deemed to be University
- Department of Radiology, SBKS MI & RC, Dhiraj Hospital, Piparia, Vadodara, India.

**iii. Related approvals:** Sumandeep Vidyapeeth Institutional ethical committee

**iv**. **Sample description:**

The reference is taken from the study conducted by **Ariji Y *et al.*,**[20] Considering 0.6 mean difference of stiffness between two groups (Healthy and Patients with TMDs) with SD 1.345.

The sample size is calculated by the formula n = 2*Z2*SD2/d2. where, Z = 2.802d = 0.6 (mean difference) SD = 1.345. Based on the above formula, minimum 160 subjects (80 cases and 80 controls) are required for present study with 95% confidence and 80% power

**v. Study Group:** The study group will include both male and female patients.

Total Participants of this study shall be 160 divided into two groups as follows:

1. Group A: 80 patients with TMDs (Patients with Myofascial pain (IA) and Myofascial pain with limited mouth opening (I B) will be included in the study
2. Group B: 80 Control patients

**vi. Time scale of Study**: One and half year from the date of approval

**vii. Selection Criteria:**

**A. Inclusion criteria-**

1. The Diagnostic Criteria for Temporomandibular disorders (DC/TMD) Axis I will be used for the classification
2. Patients with Myofascial pain will be included in the study.
3. Both male and female patients aged between 18 to 50 years will be included in the study
4. Healthy controls comprising of 80 adult healthy volunteers (age, 18–50 years) with normal teeth and jaws, who will not be classified into groups I/II/III by DC/TMD, with no history of jaw movement dysfunction, pain in the temporomandibular joint, abnormalities in mouth opening, trauma or surgery involving TMJ over the previous 3 months and who agree to participate in this study

**B. Exclusion criteria-**

1.Participants who refused to give a written consent will be excluded from the study.

2.Terminally ill patients or patients with chronic morbidity will be excluded.

3.Patients with neurological diseases like stroke, cerebral palsy and parkinsonism.

4.Patients with pregnancy, bone diseases, systemic diseases, cancer, acute pain, a history of drug ingestion within the past week (e.g., analgesics, muscle relaxants and anti-inflammatory drugs)

5.Patients with psychiatric morbidities or patients on an antipsychotic medication

6.Patients with restricted mouth opening because of odontogenic infections

7.Participants with severe illness, unable to communicate, lunatic and uncooperative patients will be excluded from the study.

8.Participants with history of head and neck trauma and Ototoxicity.

## II. Instruments/Equipment used for the study:

### A. For Clinical examination:

- Mouth mirror
- Probe
- Tweezer
- Explorer
- Vernier Calliper

B. **Personal Protective equipment**

- Head cap
- N 95 mask
- Face shield
- Surgical gown
- Gloves
- Foot cover

C. **Portable Muscle Hardness meter** (NEUTONE TDM-N1; TRY-ALL Corp., Chiba, Japan)

D.**LOGIQ P9** (GE Healthcare, Tokyo, Japan) Sonographic machine equipped with a 4.5–15 MHz wide bandwidth linear active-matrix transducer (ML6-15-D).

## III.METHODOLOGY:

1. The Permission to undertake this Study will be obtained from the Institutional Ethics Committee of Sumandeep Vidyapeeth Deemed to be University.
2. The information about this Study will be given to each participant in the vernacular language or in the language of understanding through Information Sheet. The participation in this study will be Voluntary. The Informed Consent form (in Gujarati/Hindi/ or English) will be signed by each participant who wishes to participate in this study.
3. Patients with complain of pain on the face, preauricular region and around the temple region will be subjected to Temporomandibular joint examination.
4. The clinical classification of Myofascial pain will be according to the Diagnostic Criteria for Temporomandibular disorders (DC/TMD) Axis I[23]
    - Pain of muscle origin that is affected by jaw movement, function, or parafunction, and replication of this pain occurs with provocation testing of the masticatory muscles
    - Pain in the jaw, temple, in the ear, or in front of ear
    - Pain modified with jaw movement, function, or parafunction.
    - Confirmation of pain location(s) in the temporalis or masseter muscle(s); and
    - Report of familiar pain with palpation of the temporalis or masseter muscle(s); and
5. Patients with Myofascial pain diagnosed according to the DC/TMD classification will be included in the study.
6. A detailed case history proforma will be recorded including evaluation of masticatory muscles, pain intensity and maximum assisted mouth opening. (Annexure I) The pain intensity will be calculated on a scale of 1 to 10.

7. Each subject will be seated comfortably upright in a chair at rest occlusion. The portable muscle hardness meter will be used for quantitative measurements of the muscle stiffness using an indentation method, with a measurement range of 0–50 N. The hardness of the bilateral masseter muscles will be measured for two points at the middle level of the muscles. The values at the two points will be averaged. These measurements will be performed by the PhD Scholar
8. The patients will be subjected to Ultrasound elastography.
9. The Ultrasound and Ultrasound elastography measurement will be performed by two General Radiologists, in view of the PCPNDT act. Measurements will be conducted with the subjects in a sitting position with the head held in a natural position. The bilateral masseter muscles at rest will be scanned perpendicularly to the anterior border of each muscle.
10. Sonographic elastography will be performed using the **LOGIQ P9** machine and transducer. The optimal compression pressure will be applied by monitoring the elastic scale on the left edge of the sonographic electrograms. The region of interest (ROI) for each sonographic elastogram will be placed in a manner to minimize the influence of the mandible
11. **Masseter Muscle thickness**- The Region of interest will be set in the central part of the thickness of the masseter muscle body, and depth from the epidermis will be recorded. Mean value of three measurements of the masseter muscle thickness, defined as the maximal distance between the outer fascia and the lateral surface of the ramus, were used for analyses.
12. **The Elasticity Index (EI)** will be measured using the software equipped with the LOGIQ P9 machine. The EI is generally defined as the relative elasticity of the target tissue to that of the surrounding anatomic structures.[24,25] In the present study, the target tissue is the masseter muscle and the reference tissue is the subcutaneous fat, because the subcutaneous fat was simultaneously described with the masseter muscle
13. The EIs will be measured in the masseter muscle and the subcutaneous fat tissue of the masseter muscle after setting ROIs of arbitrary sizes.
14. The **Masseter muscle elasticity index (MEI)** ratio will be calculated as the ratio of the mean EI of the masseter muscle to the mean EI of the subcutaneous fat tissue.
15. The scans will be obtained at rest and during jaw clenching with maximum force. Each measurement will be performed twice by the Radiologists and the two measurements will be averaged.
16. The measurements will be performed by two Radiologists. The MEI will be performed both on the right and left side for each patient.
17. Additionally, color coding of the masseter muscle will also be recorded to assess the stiffness.

## INFORMED CONSENT FORM (ICF) FOR PARTICIPANTS IN RESEARCH

Comparative Evaluation of Masseter Muscle stiffness by Muscle hardness meter and Ultrasound elastography in patients with Temporomandibular disorders -A case control study

**Subject's initial:** **Subject's Name:**

**Date of Birth/ Age:**

**Address of the Subject**

**Qualification:**

**Occupation: Student/ Self-Employed/ Service/ House-wife/Others: (Please tick as appropriate)**

**Annual Income of the Subject:**

| | | |
|---|---|---|
| **I.** | **I confirm that I have read and understood the information sheet dated _____for the above study and have had the opportunity to ask questions.** | ☐ |
| **II.** | **I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.** | ☐ |
| **III.** | **I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it,even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.** | ☐ |
| **IV.** | **I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)** | ☐ |
| **V.** | **The cost of the study will be borne by the Principal investigator** | ☐ |
| **VI.** | **I agree to take part in the above study.** | ☐ |

**Signature or Thumb impression of the Subject/LAR with date:**

**Signatory's Name:**

**Signature of the Investigator and date:**

**Study Investigator's Name:**

**Name, Signature of the Witness and date:**

# સંશોધનમાં સહભાગીઓ માટે જાણિત સંમતિ ફોર્મ

ટેમ્પોરોમેન્ડિબ્યુલર ડિસઓર્ડર ધરાવતા દર્દીઓમાં સ્નાયુ કઠિનતા મીટર અને અલ્ટ્રાસાઉન્ડ ઇલાસ્ટોગ્રાફી દ્વારા માસસ્ટર સ્નાયુની જડતાનું તુલનાત્મક મૂલ્યાંકન - કેસ નિયંત્રણ અભ્યાસ

સહભાગીઓ પ્રારંભિક : સહભાગીઓનું નામ:

ઉંમર: _____

સરનામું: _____

લાયકાત: _____

વ્યવસાય: વિદ્યાર્થી/સ્વ-રોજગાર/સેવા/ગૃહ-પત્ની/અન્ય: (કૃપા કરીને યોગ્ય તરીકે ટિક કરો)

વાર્ષિક આવક: _____

૧. હું પુષ્ટિ કરું છું કે મેં ઉપરોક્ત અભ્યાસ માટે _____ તારીખની માહિતી પત્રક વાંચી અને સમજી લીધી છે અને મને પ્રશ્નો પૂછવાની તક મળી છે. ☐

૨. હું સમજું છું કે અભ્યાસમાં મારી સહભાગિતા સ્વૈચ્છિક છે અને હું કોઈપણ સમયે, કોઈપણ કારણ આપ્યા વિના, મારી તબીબી સંભાળ અથવા કાનૂની અધિકારોને અસર કર્યા વિના, પાછી ખેંચવા માટે સ્વતંત્ર છું. ☐

૩.હું સમજું છું કે ક્લિનિકલ ટ્રાયલના પ્રાયોજક, પ્રાયોજક વતી કામ કરતા અન્ય, એથિક્સ કમિટી અને નિયમનકારી સત્તાવાળાઓને વર્તમાન અભ્યાસ અને અન્ય કોઈપણ સંશોધનના સંદર્ભમાં મારા સ્વાસ્થ્ય રેકોર્ડ્સ જોવા માટે મારી પરવાનગીની જરૂર રહેશે નહીં. તેના સંબંધમાં હાથ ધરવામાં આવશે, ભલે હું અજમાયશમાંથી ખસી લઉં. હું આ ઍક્સેસ માટે સંમત છું. જો કે, હું સમજું છું કે મારી ઓળખ તૃતીય પક્ષોને જાહેર કરવામાં આવેલી અથવા પ્રકાશિત કરવામાં આવેલી કોઈપણ માહિતીમાં જાહેર કરવામાં આવશે નહીં. ☐

૪. હું આ અભ્યાસમાંથી ઉદ્ભવતા કોઈપણ ડેટા અથવા પરિણામોના ઉપયોગને પ્રતિબંધિત ન કરવા માટે સંમત છું જો કે આવો ઉપયોગ માત્ર વૈજ્ઞાનિક હેતુ(ઓ) માટે જ હોય. ☐

૫. અભ્યાસનો ખર્ચ મુખ્ય તપાસનીસ દ્વારા ઉઠાવવામાં આવશે ☐

૭. હું ઉપરોક્ત અભ્યાસમાં ભાગ લેવા માટે સંમત છું. ☐

તારીખ સાથે સહભાગી ની સહી અથવા અંગૂઠાની છાપ:

સહી કરના રનું નામ ..... તારીખ.....

સંશોધન કર્તાની સહી, નામ ..... તારીખ.....

અભ્યાસ સંશોધકનું નામ ..... તારીખ.....

નામ, સાક્ષીની સહી અને તારીખ ..... તારીખ.....

## अनुसंधान में प्रतिभागियों के लिए सूचित सहमति प्रपत्र

टेम्पोरोमैंडिबुलर विकारों वाले रोगियों में मांसपेशियों की कठोरता मीटर और अल्ट्रासाउंड इलास्टोग्राफी द्वारा मास्सेटर मांसपेशियों की कठोरता का तुलनात्मक मूल्यांकन - एक केस नियंत्रण अध्ययन

**रोगीकानाम: _____**

**जन्मतिथि/उम्र :_____**

**पता:_____**

**योग्यता:_____**

**व्यवसाय: छात्र/ स्वनियोजित/ सेवा/ गृहिणी /अन्य:**

**वार्षिकआमदनी:_____**

**१. मैं पुष्टि करता/करती हूं कि मैंने उपरोक्त अध्ययन के लिए दिनांक _____ के सूचना पत्र को पढ़ और समझ लिया है और मुझे प्रश्न पूछने का अवसर मिला है** ☐

**२. मैं समझता/समझती हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और मैं बिना कोई कारण बताए, मेरी चिकित्सा देखभाल या कानूनी अधिकारों को प्रभावित किए बिना किसी भी समय वापस लेने के लिए स्वतंत्र हूं।** ☐

**३. मैं समझता हूं कि नैदानिक परीक्षण के प्रायोजक, प्रायोजक, नैतिकता समिति और नियामक प्राधिकरणों की ओर से काम करने वाले अन्य लोगों को वर्तमान अध्ययन और किसी भी अन्य शोध के संबंध में मेरे स्वास्थ्य रिकॉर्ड को देखने के लिए मेरी अनुमति की आवश्यकता नहीं होगी। इसके संबंध में, भले ही मैं परीक्षण से हट जाऊं। मैं इस पहुंच के लिए सहमत हूं। हालांकि, मैं समझता हूं कि तीसरे पक्ष को जारी या प्रकाशित किसी भी जानकारी में मेरी पहचान प्रकट नहीं की जाएगी** ☐

**४. इस अध्ययन से उत्पन्न होने वाले अन्य डेटा या परिणामों के उपयोग को प्रतिबंधित नहीं करता हू,बशर्ते ऐसा उपयोग केवल वैज्ञानिक उद्देश्यों के लिए हो।** ☐

**५. अध्ययन की लागत मुख्य अन्वेषक द्वारा वहन की जाएगी।** ☐

**६. मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हू** ☐

**हस्ताक्षर/अंगूठेकानिशानतारीख:_____**

**हस्ताक्षरकर्ताकानाम:_____**

**अन्वेषक के हस्ताक्षर:_____**

**गवाहकानाम, हस्ताक्षर,तारीख:_____**

## Participants Information Sheet

Protocol No:

Study Title: Comparative Evaluation of Masseter Muscle stiffness by Muscle hardness meter and Ultrasound elastography in patients with Temporomandibular disorders -A case control study

1.**Introduction:**

- Temporomandibular disorders (TMDs) are a group of musculoskeletal disorders that affect the stomatognathic system. TMDs is an umbrella term that embraces chronic pain conditions and dysfunction in the orofacial region affecting the masticatory muscles, the temporomandibular joints and their associated structures. TMD is frequently linked to pain that originates in the muscles. The masticatory muscle examination is very valuable for diagnosing and monitoring muscle-related temporomandibular disorders and are commonly referred as Myofascial pain.In Myofascial pain the muscles become stiff and cause facial pain affecting the quality of life in patients with TMDs. Till date physical examination by palpation is the only method for diagnosing the muscle stiffness. Various devices have been used to test the muscle stiffness but failed to achieve good results.

2.What is the purpose of this study?

- To evaluate and compare the stiffness of masseter muscles by muscle hardness meter and strain wave elastography in patients with Temporomandibular disorders and adult healthy volunteers

3.Why have I been chosen?

- As you have been diagnosed with Temporomandibular disorder.

4.Do I have to take part?

- The participation in this study is voluntary. If you are willing to participate after going through the information given here then you have to give your written consent.

5.How long will the study last?

- The present study will be completed two years however you will be completing the examination and sonoelastography procedure in 30 minutes.

6.What will happen to me if I take part?

- No untoward incident will happen. You will come to know the status of your masticatory muscles.

7.What do I have to do?

- You have to provide the consent and undergo intraoral examination and sonoelastography procedure.

8.What is the drug being tested?

- No drug is being tested in the present study.

9.What are the benefits of the study?

- We will be able to assess if you have any stiffness in the masticatory muscles

10. What are the alternatives for treatment?

- No treatment modality is being tested.

11. What are the side effects of the treatment received during the study?

- As no treatment is involved there will be no side effects

12.What if new information becomes available?

- It will be informed to you accordingly

13.What happens when the study stops?

- There are no feasibility issues in the present study. The study will be completed successfully within the time frame. In case of any eventuality, will be informed to Sumandeep Vidyapeeth Institutional ethics committee and to each participant.

14.What if something goes wrong?

- There are no risk factors in the study.

15.Will my taking part be kept confidential?

- Yes. Your participation in this study will be confidential.

16.What else should I know?

- The collected data, photographs, results& observations of this study will be used for scientific presentation, publications and for record keeping.

17.Additional Precaution

- No precautions are required.

18.Whom to call with questions?

- If there is any query related to study, than you may contact the Principal Investigator Dr Deepa Patil on +91-8847457128 or ay send your queries on iafdeepa@gmail.com

સહભાગીઓ માહિતી શીટ

પ્રોટોકોલ નંબર:

અભ્યાસનું શીર્ષક: ટેમ્પોરોમેંડીબુલર વિકૃતિઓ વાળા રોગીઓમાં માંસપેશીઓની કડકતા મીટર અને અલ્ટ્રાસાઉંડ ઇલાસ્ટોગ્રાફી દ્વારા માસ્સેટર માંસપેશીઓની કડકતાનું તુલનાત્મક મૂલ્યાંકન - એક કેસ નિયંત્રણ અભ્યાસ

1. પરિચય:

ટેમ્પોરોમેન્ડિબ્યુલર ડિસઓર્ડર (TMDs) એ મસ્ક્યુલોસ્કેલેટલ ડિસઓર્ડરનું એક જૂથ છે જે સ્ટોમેટોગ્નેથિક સિસ્ટમને અસર કરે છે. TMDs એ એક છત્ર શબ્દ છે જે ઓરોફેસિયલ પ્રદેશમાં ક્રોનિક પીડાની સ્થિતિ અને નિષ્ક્રિયતાને સ્વીકારે છે જે મેસ્ટિકેટરી સ્નાયુઓ, ટેમ્પોરોમેન્ડિબ્યુલર સાંધા અને તેમની સંલગ્ન રચનાઓને અસર કરે છે. TMD વારંવાર સ્નાયુઓમાં ઉદ્ભવતી પીડા સાથે જોડાયેલું છે. સ્નાયુ-સંબંધિત ટેમ્પોરોમેન્ડિબ્યુલર ડિસઓર્ડરનું નિદાન કરવા અને તેનું નિરીક્ષણ કરવા માટે મસ્ટિકેટરી સ્નાયુની પરીક્ષા ખૂબ જ મૂલ્યવાન છે અને તેને સામાન્ય રીતે માયોફેસિયલ પેઇન તરીકે ઓળખવામાં આવે છે. માયોફેસિયલ પેઇનમાં સ્નાયુઓ જકડાઈ જાય છે અને TMD ધરાવતા દર્દીઓના જીવનની ગુણવત્તાને અસર કરતા ચહેરાના દુખાવાનું કારણ બને છે. સ્નાયુઓની જડતાના નિદાન માટે પેલ્પેશન એ એકમાત્ર પદ્ધતિ છે. સ્નાયુઓની જડતા ચકાસવા માટે વિવિધ ઉપકરણોનો ઉપયોગ કરવામાં આવ્યો છે પરંતુ સારા પરિણામો પ્રાપ્ત કરવામાં નિષ્ફળ ગયા છે.

2. આ અભ્યાસનો હેતુ શું છે?

**ટેમ્પોરોમેન્ડિબ્યુલર ડિસઓર્ડર ધરાવતા દર્દીઓ અને પુખ્ત સ્વસ્થ સ્વયંસેવકોમાં સ્ટ્રેઈન વેવ**

ઈલાસ્ટોગ્રાફી દ્વારા માસસેટર સ્નાયુઓની જડતાનું મૂલ્યાંકન અને તુલના કરવા માટે

3. મને શા માટે પસંદ કરવામાં આવ્યો છે?

જેમ કે તમને ટેમ્પોરોમેન્ડિબ્યુલર ડિસઓર્ડર હોવાનું નિદાન થયું છે.

4. શું મારે ભાગ લેવો પડશે?

આ અભ્યાસમાં સહભાગિતા સ્વૈચ્છિક છે. જો તમે અહીં આપેલી માહિતીને જોયા પછી ભાગ લેવા તૈયારછો તો તમારે તમારી લેખિત સંમતિ આપવી પડશે.

5. અભ્યાસ કેટલો સમય ચાલશે?

વર્તમાન અભ્યાસ બે વર્ષ પૂર્ણ થશે જો કે તમે 30 મિનિટમાં પરીક્ષા અને સોનોએલાસ્ટોગ્રાફી પ્રક્રિયા પૂર્ણ કરશો.

6. જો હું ભાગ લઉં તો મારું શું થશે?

કોઈ અનિચ્છનીય બનાવ બનશે નહીં. તમે તમારા મસ્તિક સ્નાયુઓની સ્થિતિ જાણી શકશો.

7. મારે શું કરવાનું છે?

તમારે સંમતિ આપવી પડશે અને ઇન્ટ્રાઓરલ પરીક્ષા અને સોનોએલાસ્ટોગ્રાફી પ્રક્રિયામાંથી પસાર થવું પડશે.

8.દવાનું શું પરીક્ષણ કરવામાં આવે છે?

વર્તમાન અભ્યાસમાં કોઈ દવાનું પરીક્ષણ કરવામાં આવ્યું નથી.

9. અભ્યાસના ફાયદા શું છે?

જો તમને મેસ્ટિકેટરી સ્નાયુઓમાં કોઈ જડતા છે કે કેમ તે અમે આકારણી કરી શકીશું

10. સારવાર માટેના વિકલ્પો શું છે?

સારવારની કોઈ પદ્ધતિનું પરીક્ષણ કરવામાં આવ્યું નથી.

11. અભ્યાસ દરમિયાન પ્રાપ્ત સારવારની આડઅસર શું છે?

કોઈપણ સારવાર સામેલ ન હોવાથી કોઈ આડઅસર થશે નહીં

12. જો નવી માહિતી ઉપલબ્ધ થાય તો શું?

તે મુજબ તમને જાણ કરવામાં આવશે

13. જ્યારે અભ્યાસ બંધ થઈ જાય ત્યારે શું થાય છે?

હાલના અભ્યાસમાં સંભવિતતાની કોઈ સમસ્યા નથી. અભ્યાસ સમયમર્યાદામાં સફળતાપૂર્વક પૂર્ણ

થશે. કોઈ પણ સંજોગોમાં, સુમનદીપ વિદ્યાપીઠ સંસ્થાકીય નીતિશાસ્ત્ર સમિતિ અને દરેક સહભાગીન જાણ કરવામાં આવશે.

14. જો કંઈક ખોટું થાય તો શું?

અભ્યાસમાં કોઈ જોખમી પરિબળો નથી.

15. શું મારો ભાગ લેવાનું ગુપ્ત રાખવામાં આવશે?

હા. આ અભ્યાસમાં તમારી ભાગીદારી ગોપનીય રહેશે.

16.મારે બીજું શું જાણવું જોઈએ?

આ અભ્યાસના એકત્રિત ડેટા, ફોટોગ્રાફ્સ, પરિણામો અને અવલોકનોનો ઉપયોગ વૈજ્ઞાનિક પ્રસ્તુતિ, પ્રકાશનો અને રેકોર્ડ રાખવા માટે કરવામાં આવશે.

17. વધારાની સાવચેતી:

કોઈ સાવચેતીની જરૂર નથી.

18. પ્રશ્નો સાથે કોને કૉલ કરવો?

જો અભ્યાસ સંબંધિત કોઈ પ્રશ્ન હોય, તો તમે +91-8847457128 પર પ્રિન્સિપલ ઈન્વેસ્ટિગેટર ડૉ. દીપા પાટીલનો સંપર્ક કરી શકો છો અથવા તમારા પ્રશ્નો iafdeepa@gmail.com પર મોકલી શકો છો.

## प्रतिभागियों की सूचना पत्र

प्रोटोकॉल संख्या:

अध्ययन शीर्षक: टेम्पोरोमैंडिबुलर विकारों वाले रोगियों में मांसपेशियों की कठोरता मीटर और अल्ट्रासाउंड इलास्टोग्राफी द्वारा मास्सेटर मांसपेशियों की कठोरता का तुलनात्मक मूल्यांकन - एक केस नियंत्रण अध्ययन

1 परिचय:

टेम्पोरोमैंडिबुलर डिसऑर्डर (TMDs) मस्कुलोस्केलेटल विकारों का एक समूह है जो स्टोमेटोगैथिक सिस्टम को प्रभावित करता है। TMDs एक छत्र शब्द है जो पुराने दर्द की स्थिति और ओरोफेशियल क्षेत्र में शिथिलता को प्रभावित करता है जो चबाने वाली मांसपेशियों, टेम्पोरोमैंडिबुलर जोड़ों और उनकी संबंधित संरचनाओं को प्रभावित करता है। टीएमडी अक्सर दर्द से जुड़ा होता है जो मांसपेशियों में उत्पन्न होता है। मांसपेशियों से संबंधित टेम्पोरोमैंडिबुलर विकारों के निदान और निगरानी के लिए चबाने वाली मांसपेशी परीक्षा बहुत मूल्यवान है और इसे आमतौर पर मायोफेशियल दर्द के रूप में जाना जाता है। मायोफेशियल दर्द में मांसपेशियां सख्त हो जाती हैं और चेहरे के दर्द का कारण टीएमडी वाले रोगियों में जीवन की गुणवत्ता को प्रभावित करती हैं। पैल्पेशन मांसपेशियों की अकड़न का निदान करने का एकमात्र तरीका है। मांसपेशियों की कठोरता का परीक्षण करने के लिए विभिन्न उपकरणों का उपयोग किया गया है लेकिन अच्छे परिणाम प्राप्त करने में विफल रहे हैं।

2. इस अध्ययन का उद्देश्य क्या है?

टेम्पोरोमैंडिबुलर विकारों और वयस्क स्वस्थ स्वयंसेवकों के रोगियों में तनाव तरंग इलास्टोग्राफी द्वारा मासपेशियों की मांसपेशियों की कठोरता का मूल्यांकन और तुलना करना

3. मुझे क्यों चुना गया है?

जैसा कि आपको टेम्पोरोमैंडिबुलर डिसऑर्डर का पता चला है।

4. क्या मुझे भाग लेना है?

इस अध्ययन में भागीदारी स्वैच्छिक है। यदि आप यहां दी गई जानकारी को पढ़कर भाग लेने के इच्छुक हैं तो आपको अपनी लिखित सहमति देनी होगी।

5. अध्ययन कब तक चलेगा?

वर्तमान अध्ययन को दो वर्ष पूरे होंगे लेकिन आप 30 मिनट में परीक्षा और सोनोलास्टोग्राफी प्रक्रिया पूरी कर लेंगे।

6. यदि मैं भाग लेता हूँ तो मेरा क्या होगा?

कोई अप्रिय घटना नहीं होगी। आपको अपनी चबाने वाली मांसपेशियों की स्थिति का पता चल जाएगा।

7. मुझे क्या करना होगा?

आपको सहमति प्रदान करनी होगी और अंतर्गर्भाशयी परीक्षा और सोनोलेस्टोग्राफी प्रक्रिया से गुजरना होगा।

8. किस दवा का परीक्षण किया जा रहा है?

वर्तमान अध्ययन में किसी दवा का परीक्षण नहीं किया जा रहा है।

9. अध्ययन के क्या लाभ हैं?

हम यह आकलन करने में सक्षम होंगे कि क्या आपको चबाने वाली मांसपेशियों में कोई कठोरता है

10. उपचार के विकल्प क्या हैं?

उपचार के तौर-तरीकों का परीक्षण नहीं किया जा रहा है।

11. अध्ययन के दौरान प्राप्त उपचार के क्या दुष्प्रभाव हैं?

चूंकि कोई उपचार शामिल नहीं है, इसलिए कोई दुष्प्रभाव नहीं होगा

12. क्या होगा यदि नई जानकारी उपलब्ध हो जाती है?

इसके अनुसार आपको सूचित किया जाएगा

13. क्या होता है जब अध्ययन बंद हो जाता है?

वर्तमान अध्ययन में कोई व्यवहार्यता मुद्दे नहीं हैं। समय सीमा के भीतर अध्ययन सफलतापूर्वक पूरा कर लिया जाएगा। किसी भी घटना के मामले में, सुमनदीप विद्यापीठ संस्थागत आचार समिति और प्रत्येक प्रतिभागी को सूचित किया जाएगा।

14. अगर कुछ गलत हो जाए तो क्या होगा?

अध्ययन में कोई जोखिम कारक नहीं हैं।

15. क्या मेरे भाग लेने को गोपनीय रखा जाएगा?

हां। इस अध्ययन में आपकी भागीदारी गोपनीय रहेगी।

16. मुझे और क्या पता होना चाहिए?

इस अध्ययन के एकत्रित आंकड़ों, तस्वीरों, परिणामों और टिप्पणियों का उपयोग वैज्ञानिक प्रस्तुति, प्रकाशन और रिकॉर्ड रखने के लिए किया जाएगा।

17. अतिरिक्त सावधानी:

कोई सावधानियों की आवश्यकता नहीं है।

18. प्रश्नों के साथ किसे कॉल करें?

यदि अध्ययन से संबंधित कोई प्रश्न है, तो आप प्रधान अन्वेषक डॉ दीपा पाटिल से +91-8847457128 पर संपर्क कर सकते हैं या अपने प्रश्न iafdeepa@gmail.com पर भेज सकते हैं।

**CASE HISTORY PROFORMA**

**Department of Oral Medicine & Radiology, KMSDCH& Department of Radiology SBKS MI & RC Sumandeep Vidyapeeth Deemed to be University, Piparia.**

**Comparative Evaluation of Masseter Muscle stiffness by Muscle hardness meter and Ultrasound elastography in patients with Temporomandibular disorders -A case control study**

Name: OPD No.:

Age: Gender:

Occupation: Address:

Date: Phone no:

Chief complaint:

History of present Illness:

Medical History:

Personal Habits: -

Bruxism:

I. CLINICAL EVALUATION –

a) Significant Extraoral findings –

b) TMJ Examination:

Tenderness in preauricular region:

Tenderness in Muscles of mastication:

Deviation/Deflection:

Provocative test:

Joint sounds:

Hard end feel/Soft end feel:

Mouth opening:

Maximum assisted mouth opening

c) Significant Intraoral findings

d) Visual Analogue scale for pain:

Clinical Diagnosis –

Value of Muscle stiffness by Hardness meter

II. ELASTOGRPAHIC EVALUATION

Examiner 1

| | **Masseter Muscle thickness** | **EI of Masseter** | **EI of Subcutaneous fat** | **Masseter muscle elasticity index (MEI) ratio** |
|---|---|---|---|---|
| Right Masseter | | | | |
| Left Masseter | | | | |

Examiner 2

| | **Masseter Muscle thickness** | **E1 of Masseter** | **E1 of Subcutaneous fat** | **Masseter muscle elasticity index (MEI) ratio** |
|---|---|---|---|---|
| Right Masseter | | | | |
| Left Masseter | | | | |

III. Clinical Interpretation:

IV. Recommendations:

Place of study: Date: _____

Name and Signature of PhD Scholar: _____

Name and Signature of Research Supervisor/Co-Supervisor: _____

**Statistical analysis:**

The collected data of each participant will be entered in the Master chart prepared in the Microsoft Excel sheet on the computer. Statistical analysis will be conducted by using the latest SPSS software version. Descriptive statistical methods will be used for evaluation of the data. - Independent t-test will be used to compare variables between two groups. Intraobserver analysis will be done through intraclass coefficient. Spearman's rank correlation coefficient will be applied to evaluate the relationships between the muscle hardness meter and elastography values and the values between patients and healthy volunteers.

**Ethical issues:**

- The permission for the study will be obtained from Institutional Ethics Committee.
- The informed consent will be obtained from each participant and the confidentiality of the data will be maintained.

**Likely outcome of the Study:**

A valuable diagnostic tool in the form of muscle hardness meter and elastography can be evaluated to diagnose muscle stiffness in patients with Myofascial pain. The results obtained from the study can form a baseline data to compare stiffness between patients with TMDs (Myofascial pain) and controls. The data obtained can help the clinicians in better diagnosis and formulating tailored treatment protocol for these patients. This can help in deciding the effective treatment plan for the patients with Myofascial pain thereby reducing the pain intensity and improving their quality of life.

**Conflict of Interest:** Nil

**Sponsors for the study:** Self

**Source of fund:** Self

**Expenditure statement:**

Total expenditure-98,600/-

- Muscle Hardness meter-33,000
- Elastography procedure per patient- 285x 160= 45600
- Printing and Binding charges-20,000/-
- Statistical analysis- 5,000/-

**Place of work and facilities available**

- **Place of study and Source of Data:**

  The study will be conducted at:

  - Department of Oral Medicine & Radiology, KMSDCH, Sumandeep Vidyapeeth deemed to be University
  - Department of Radiology, Dhiraj Hospital, Sumandeep Vidyapeeth deemed to be University, Piparia, Vadodara, India.

- The Out Patient Division of Department of Oral Medicine and Radiology, K.M. Shah Dental College and Hospital, Sumandeep Vidyapeeth Deemed University; routinely records patients with complaint of Temporomandibular joint pain. These patients are diagnosed and treated in the department on a regular basis. The participants required for the study will be recruited from the Department of Oral Medicine and Radiology, K. M. Shah Dental College and Hospital, Sumandeep Vidyapeeth Deemed to be University, Piparia, Vadodara.
- Department of Radiology is well equipped with USG machines and sonographic examinations are performed by experienced radiologists. After recording the detailed Case history and diagnosis of Myofascial pain the study participants will be subjected to Sonography examination, at Department of Radiology, Dhiraj Hospital, Sumandeep Vidyapeeth deemed to be University, Piparia, Vadodara, India.

## PATENTS

- Based on the results obtained from the cases and controls a new classification will be proposed based on the values obtained by elastography to assess the stiffness of Masseter muscle in patients with myofascial pain and healthy adults.
- A novel color coded elastogram depicting the muscle stiffens and taut muscle trigger bands can be designed for TMD patients with Myofascial pain

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**For the purpose of synopsis submission**

Title: **Comparative Evaluation of Masseter Muscle stiffness by Muscle hardness meter and Ultrasound elastography in patients with Temporomandibular disorders -A case control study**


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